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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,619	01/23/2004	Tillmann Rumenapf	G-31109B	7290

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ONE HEALTH PLAZA 104/3
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EXAMINER	
MOORE, WILLIAM W	
ART UNIT	**PAPER NUMBER**
1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/763,619	RUMENAPF ET AL.	
	Examiner	Art Unit	
	William W. Moore	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Applicant's Amendments to the specification and claims in the Response 11 April 2007 have been entered. The cancellation of claim 13 removes the basis for the obviousness-type double patenting rejection herein, which is withdrawn, and the claim amendments remove the basis for the rejection of record of claims herein over the prior at of record and the rejections of certain claims herein as indefinite for recitations of one or more acronyms and for a poor description of the relationship of fusion partners in a fusion polypeptide. The amendments to claims 1-8, 10 and 11 advance prosecution by removing the basis for the objection of record of claims 8-13 under 37 CFR 1.75(c) for improper, multiple, dependency, and this objection is withdrawn. The claim amendments also remove the basis for the objection of record of claim 4 under 37 CFR 1.75(c) for failing to limit the scope of claim 1 from which it depends. The claim amendments do not, however, remedy the improper dependency of claims 5 and 6 from claim 1, which objection is renewed, nor do they adequately address the rejections of record of claims herein under the first paragraph of 35 U.S.C. § 112 and the primary rejection affecting all claims pending herein under the second paragraph of 35 U.S.C. § 112. Claim

Claim Objections

Claims 5 and 6 remain objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The recitations in claims 5 and 6 "or a derivative thereof having the autoproteolytic activity of the autoprotease N^{PRO} of classic swine fever virus", remove any distinction between polynucleotides of these claims and a polynucleotide of claim 1 encoding the amino acid sequence of a generic pestivirus autoprotease N^{PRO} where claims 5 and 6 fail to otherwise indicate any functional or structural difference between an autoproteolytic activity of a classic swine fever virus autoprotease N^{PRO} and the autoproteolytic activity of a generic pestivirus autoprotease N^{PRO}, and no such distinction is disclosed in the specification. Because claims 5 and 6 cannot further limit the subject matter of claim 1 from which they depend, amending claims 5 and 6 to delete the phrase, "or a derivative thereof having the autoproteolytic activity of the autoprotease N^{PRO} of classic swine fever virus", is required in order to overcome this objection by placing claims 5 and 6 in proper dependent form.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 remain rejected for reasons of record under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's arguments in the Response filed 11 April 2007 have been fully considered but they are not persuasive. Applicant suggests at pages 6 and 7 of the Response that the specification need not disclose more than amino-terminal amino acid sequence truncations to adequately describe "derivative[s] . . . having the autoproteolytic activity" of a generic pestivirus autoprotease N^{PRO}, or "having the autoproteolytic activity of the autoprotease N^{PRO} of classic swine fever virus". Applicant instead considers the specification's teaching of truncations to produce some proteolytically active fragments of the N^{PRO} autoprotease classic swine fever virus amino acid sequence set forth in SEQ ID NO:1 and the prior art teaching of Wiskerchen et al. of the roles of four amino acids in a single pestivirus autoprotease N^{PRO} to be sufficient to provide unlimited variations. Yet the specification fails to exemplify or describe the preparation of divergent pestivirus N^{PRO} proteases that far exceed deletions of the amino-proximal regions recited in claims 5 and 6 and exceed the introduction of one or few amino acid substitutions because they reach derivatives that need have no particular, or a very limited, structural relationship to the amino acid sequence set forth in SEQ ID NO:1. "While one does not need to have carried out one's invention before filing a patent application, one does need to be able to describe that invention with particularity" to satisfy the description requirement of the first paragraph of 35 U.S.C. § 112. *Fiers v. Revel v. Sugano*, 25 USPQ2d 1601, 1605 (Fed. Cir. 1993). The rejection of record is sustained because the specification's treatment of "derivatives" of pestivirus N^{PRO} autoproteases is entirely prospective.

Claims 1-12 remain rejected for reasons of record under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for the preparation of a fusion polypeptide comprising an amino-proximal pestivirus N^{PRO} autoprotease having an amino acid sequence that corresponds to the amino acid sequence from position 22 through position 168 of SEQ ID NO:1, whereby a fusion partner carboxyl-proximal to the pestivirus N^{PRO} autoprotease region may be autoproteolytically processed to produce a free protein that is not a pestivirus protein, i.e., a free heterologous protein,

does not reasonably provide enablement for the preparation of such a fusion polypeptide whereby an unspecified "derivative" of an amino-proximal pestivirus N^{PRO} autoprotease having an amino acid sequence that corresponds to the amino acid sequence from position 22 through position 168 of SEQ ID NO:1 will permit autoproteolytic processing to produce a free heterologous protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant's arguments in the Response filed 11 April 2007 have been fully considered but they are not persuasive. Applicant suggests at pages 7-9 of the Response that considers the specification's teaching of truncations of the classic swine fever virus N^{PRO} autoprotease of SEQ ID NO:1 that retain C-terminal autoproteolytic activity and the teachings of Wiskerchen et al. of the roles of four amino acids in a single pestivirus autoprotease N^{PRO} can enable the design and preparation of any kind of "derivative" that retains autoproteolytic activity. Yet claims 1, 5, and 6, and claims 2-4 and 7-12 that depend therefrom, contemplate an arbitrary number of amino acid substitutions, additions or deletions anywhere within pestivirus N^{PRO} autoprotease amino acid sequences, including modification occurring even within the core functional region corresponding to the sequence of amino acids from position 22 through position 168 of SEQ ID NO:1. See the discussion at pages 5 and 6 of the specification. Even if combined with the teachings of the prior art made of record herein the specification cannot support the introduction of an unspecified number of amino acid sequence alterations in the core, functional, region of a pestivirus N^{PRO} autoprotease amino acid sequence, in any combination or any pattern. Applicant suggests at page 9 of the Response that the availability of processes for generating combinatorial libraries reduces the amount of experimentation to a level that is no longer "undue" but, as noted in the rejection of record, the standard set by the CCPA, the precursor of the Court of Appeals for the Federal Circuit, is not to "make and screen" any and all possible alterations because a reasonable correlation must exist between the scope asserted in the claimed subject matter and the scope of guidance the specification provides. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 25 (CCPA 1970) (scope of enablement varies inversely with the degree of unpredictability of factors involved in physiological activity of small peptide hormone), and the Court of Appeals for the Federal Circuit approved this standard set by the CCPA in *Genentech, Inc. v. Novo-Nordisk A/S*, 42 USPQ2d 1001 (Fed. Cir. 1997). The rejection of record is therefore sustained.

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 remain rejected for reasons of record under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 5 and 6 remain rejected as indefinite because claims 1, 5 and 6 recite, "derivative thereof with autoproteolytic activity". These phrases indicate no characteristic other than autoproteolysis and the artisan and the public seeking to determine the metes and bounds of the intended subject matter cannot ascertain the structure of any derivatives from the specification's disclosure, particularly where the recitations, "having the autoproteolytic activity of the autoprotease N^{PRO} of classic swine fever virus", in claims 5 and 6 permit the replacement of the amino-terminal amino acids indicated as deleted with part or all of the regions removed, or with an unrelated amino acid sequence. These recitations in claims 1, 5 and 6 that provide no structure limitations imply that some form of derivative is intended other than the successive amino-terminal amino acid sequence deletions more specifically described elsewhere in claims 5 and 6, rendering the scope of the claims ambiguous, thus indefinite. This rejection may be overcome by deleting the phrases that necessitate this rejection of claims 1, 5, and 6 and claims 2-4 and 7-12 that depend therefrom.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Dr. Kathleen Kerr Bragdon, can be

reached at 571.272.0931. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

/Nashed/
Nashaat T. Nashed, Ph. D.
Primary Examiner
Art Unit 1656

William W. Moore
6 July 2007